Water Technologies & Solutions
application note

Sievers M9 Portable TOC Analyzer for maintenance and control of pharmaceutical water systems

introduction

Properly maintaining and controlling pharmaceutical water systems can be challenging. The design from generation to distribution can result in numerous points of failure that significantly reduce control of a water system. With the demand for production efficiency and push toward continuous manufacturing, utility uptime is critical. At-line or online tools for real time troubleshooting of a variety of water system issues can help mitigate risks and decrease system down time. For example, the Sievers* M9 Portable Total Organic Carbon (TOC) Analyzer can be used online and in grab mode to troubleshoot a variety of water system issues and provide essential details on system performance.

Sievers Membrane Conductometric (MC) technology is highly accurate and can be fully validated per USP <1225>. With quantitative data obtained using a Sievers TOC Analyzer, decisions can be made regarding process control of a water system for both TOC and conductivity. MC technology is not affected by temperature, pressure, ionic interferences, or rouging and provides additional data (e.g., inorganic carbon and conductivity) that can be used as Key Process Indicators for more effective water system control.

rinse-out of a water system after sanitization with Minncare ®

Minncare is a widely-used chemical for sanitizing reverse osmosis membranes and water distribution systems. After sanitizing a water system, test strips from the chemical manufacturer demonstrate when Minncare has been flushed out to less than 1 ppm, however 1 ppm of Minncare still contains approximately 650 ppb TOC. As such, water systems that appear to be clear of Minncare must continue to be flushed until they are compliant with the USP standard for TOC (<500 ppb).

Furthermore, during normal operation most pharmaceutical water systems average between 10 and 50 ppb TOC and require even more flushing to return to normal operating conditions. Using the Sievers M9 Portable TOC Analyzer in online mode allows companies to effectively monitor the rinse-out of Minncare from a water system and ensure a complete return to normal operating conditions. Turbo Mode can also be used to provide high-resolution data and readings every four seconds during the water system flushing.

The data in **Figure 1** simulate the Minncare rinse-out of pharmaceutical water systems with the following Sievers TOC Analyzers[1]:

- 500 RL TOC Analyzer
- M9 TOC Analyzer in Normal Mode (result every two minutes)
- M9 TOC Analyzer in Turbo Mode (result every four seconds)

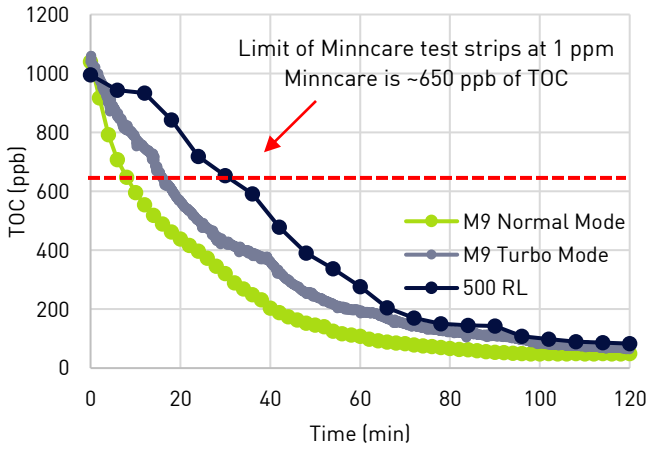


Figure 1. Simulation of pharmaceutical water system rinse-out following chemical sanitization with Minncare.

As **Figure 1** demonstrates, both the 500 RL and M9 Portable TOC Analyzers can be important tools for

determining rinse-out time following chemical sanitization. With higher flow rates on a real water system compared to the laboratory-generated data presented here, faster analysis times using Turbo Mode can be extremely useful for minimizing wastes and assisting with quick system release.

detection of a heat exchanger leak and troubleshooting of leak detection

Monitoring for leaks in pharmaceutical water system heat exchangers is critical for overall system performance, compliance, and integrity. A variety of fluids can be used as the cooling fluid in a heat exchanger, though two of the most common are ethylene glycol and refrigerated tap water. Both fluids can be detected using TOC analysis. Ethylene glycol has superior heat transfer capabilities and, as an organic molecule, is quantitatively recovered by TOC analysis. Tap water is also detected by TOC analysis, as TOC concentrations in tap water are typically >1 ppm.

In the case of clean steam condensate, a leak of ethylene glycol or tap water into the condensate can be detected by TOC analysis. Online TOC analysis of steam condensate with a Sievers M9 or 500 RL TOC Analyzer can be highly effective for detecting leaks early when corrective action can be taken before the system is compromised and/or out of compliance.

Figure 2 demonstrates the use of Sievers TOC Analyzers to provide highly comprehensive information related to a heat exchanger leak. In this example, a glycol leak was first detected using the 500 RL and the M9 Portable Analyzer running online.

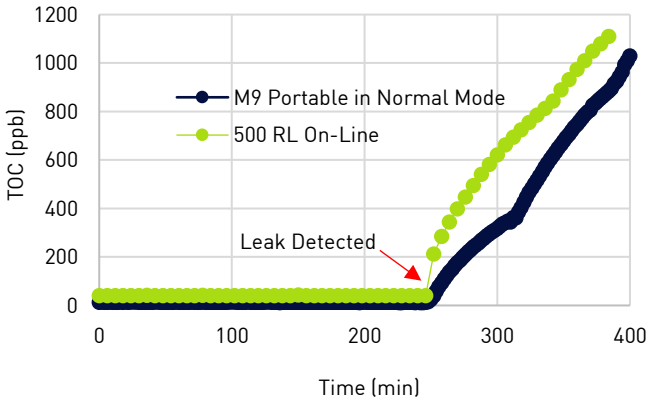
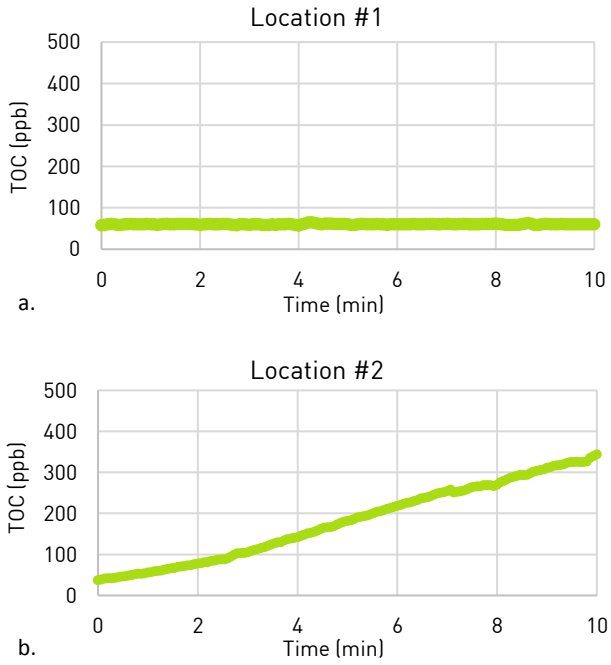


Figure 2. Use of M9 Portable and 500 RL On-Line TOC Analyzers to detect simulated ethylene glycol leak.

Following initial leak detection, the M9 Portable TOC Analyzer was used in Turbo Mode at two different locations in the system to troubleshoot and determine the location of the leak (**Figures 3a** and **3b**). Data collected over a short period with the M9 Portable in Turbo Mode can quickly pinpoint the location of the leak.



Figures 3a and 3b. Determination of leak location using the M9 Portable TOC Analyzer in Turbo Mode.

In this example, the 500 RL and M9 Portable provided equivalent quantitative TOC analysis of the water, therefore justifying the use of the M9 Portable as a temporary substitute for online water monitoring if a permanently-installed 500 RL is briefly out of commission for routine maintenance.

conclusion

Although pharmaceutical water systems can be challenging to control, tools such as the Sievers M9 Portable TOC Analyzer make monitoring and troubleshooting easier. Whether showing the rinse-out of a water system after sanitization or detecting heat exchanger leaks, the M9 Portable Analyzer can be an effective utility tool for properly maintaining pharmaceutical water systems.

1. All simulations and analysis were performed in the SUEZ Applications Lab in Boulder, CO.